

II. REMARKS

This Response is filed with a Request for Continued Examination (RCE), a two month Petition for Extension of Time, and the required fees. Applicants respectfully request entry of the Response filed on September 8, 2008.

Claims 7-12 are pending. Claims 7-10 were withdrawn from consideration by the Examiner.

By this amendment, claim 8 is canceled, and claim 7 is amended. Support for the amendment can be found in the specification and claims as originally filed. For example, support for the amendment to claim 7 can be found at least in canceled claim 8, and on page 13, line 3 of the specification. Applicants submit that no new matter has been added and respectfully request reconsideration and withdrawal of the rejections.

Rejections under 35 U.S.C. § 103

1. *Yang et al.*

Claim 11 has been rejected under 35 U.S.C. § 103(a) over Yang et al. (U.S. Patent No. 4,740,376). Applicants traverse the rejection.

Claim 11 is directed to a "method of producing solid pharmaceutical preparations, comprising using the polyvinylacetates of claim 10 as a binder, alone or in combination with other binders, in base granulates or granulates that contain an active substance, wherein the polyvinylacetates are used in a solution with solvent or as a solid powder." Applicants submit that the polyvinylacetates of claim 10 have the following claimed properties: mean molecular weight between 10,000 and 40,000 Daltons, remnant monomer content of less than 2 ppm by weight, water content less than 1.5% by weight,

total acidity referred to acetic acid less than 0.5% by weight, peroxide content of 0.0%, and glass transition temperature of 35°C to 39°C. Further, Applicants submit that claim 10 depends from claim 7, which has been currently amended to recite that polyvinylacetates are obtained by a process comprising a polymerization step in a solution comprising “ethanol, methanol, or a volatile alcohol” (step (1)) and a purification step (step (2)).

In addition to the arguments provided in the previous Response dated September 8, 2008, incorporated herein by reference, Applicants submit that the process described in the present application provides for polymers which can have higher purity than known polymers in the art. Applicants submit that on an industrial scale, it is often difficult to create polymers of high purity. Known processes of purification, such as processes that include simply heating a mixture above the boiling temperatures of the impurities and using a vacuum or melting the polymer, do not always result a proper purification at an industrial level.

Applicants further submit that the polyvinylacetates of the presently claimed invention can be used in solid pharmaceutical formulations.

Applicants submit that Yang et al. does not teach or suggest the presently claimed invention. Applicants submit that Yang et al. discloses a specific formulation with use of molten polymer. Applicants submit that one of ordinary skill in the art would understand that the simple heating of the polymer at 85°C, as disclosed by Yang et al., would not result in sufficiently pure polyvinylacetates. Applicants further submit that the step of “heating said polymer mass at a temperature between 80°C and 140°C in a

vacuum of 0.02 – 13 kPa” and stirring to reach the desired purity (claim 7) is not taught or suggested by Yang et al.

For at least the reasons stated above, Applicants submit that Yang et al. does not teach or suggest the presently claimed invention and respectfully request reconsideration and withdrawal of the rejection of claim 11 under 35 U.S.C. § 103(a) over Yang et al.

2. Sa

Claim 11 was rejected under 35 U.S.C. § 103(a) over Sa (Drug Development and Industrial Pharmacy, 17(6), 893-900 (1991)). Applicants traverse the rejection.

Claim 11 and the features of the presently claimed invention have been discussed above.

Applicants submit that Sa does not teach or suggest the presently claimed invention. In addition to the arguments presented in the previous Response dated September 8, 2008, incorporated herein by reference, Applicants submit that Sa discloses microencapsulation using polyvinylacetates (PVAc). Applicants submit that if the PVAc disclosed in Sa is not sufficiently pure, then part of the impurities would not evaporate with the acetone at the low temperatures used. Applicants submit that part of the water and monomer impurity would concentrate in the polymer mass due to chemical affinity. Applicants submit that the use of a vacuum dessicator may separate part of those impurities in a reasonable time if the temperature would be raised; however, Applicants submit that this cannot be done, since the microspheres would

agglomerate, due to its high content of polymer and the low glass transition temperature (T_g) of the polymer. Applicants further submit that Sa does not disclose an industrial procedure

For at least the reasons stated above, Applicants submit that Sa does not teach or suggest the presently claimed invention and respectfully request reconsideration and withdrawal of the rejection of claim 11 over Sa.

3. *Yang et al., in view of Sa*

Claims 11-12 were rejected under 35 U.S.C. § 103(a) over Yang et al., in view of Sa. Applicants traverse the rejection.

As discussed above, Applicants submit that the presently claimed invention is not taught by Yang et al. and Sa. Applicants submit that the deficiencies of Yang et al. are not cured by Sa, and neither reference teaches the polyvinylacetates of the presently claimed invention.

Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 11-12 under 35 U.S.C. § 103(a) over Yang et al., in view of Sa.

III. CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this response is not timely filed, the Applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other additional fees which may be required with respect to this response, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 024273-00001.

Respectfully submitted,



Yelee Y. Kim
Registration No.: 60,088

Customer No.: **004372**
ARENT FOX LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036-5339
Telephone No.: 202-857-6000
Facsimile No.: 202-857-6395

RJB/YYK:yyk